HEALTH) COMMUNICABLE DISEASES — LABORATORIES — ANONYMOUS HIV TEST SITES REMAIN PERMISSIBLE

July 26, 1993

The Honorable Paula C. Hollinger Maryland Senate

You have requested our opinion whether Chapter 66 (House Bill 460) of the Laws of Maryland 1992 requires anonymous testing sites to obtain and report to the county health officer a unique patient identifying number for those who seek to be tested for the human immunodeficiency virus ("HIV"). The question, in other words, is whether all test centers, even those that would prefer not to obtain the identifying number, must do so as a prerequisite to testing for HIV.

For the reasons set forth below, we conclude that Chapter 66 does not bar a test center from obtaining a blood specimen from a patient who declines to provide the information needed for the unique patient identifier, nor does the statute preclude a laboratory from testing a specimen that arrives at the laboratory without the unique patient identifier.

I

Background

Under §18-201(a) of the Health-General Article ("HG" Article), a physician is required to report, by "name, age, race, sex, and residence address of the patient," any "infectious or contagious disease that endangers public health" HG §18-202 requires the same kind of reporting by "institutions." Finally, HG §18-205(a) requires a medical laboratory director to report an individual by name to the health officer of the county where the laboratory is located within 48 hours after an examination if a specimen from that individual shows evidence of certain specified contagious diseases (for example, gonorrhea, viral hepatitis type A, and tuberculosis).

¹ An "institution" is a hospital or a "lodging facility." HG §18-202(a).

Although HIV infection, the precursor to AIDS, is also an infectious disease, current law establishes a quite different rule with regard to the reporting of HIV test results: "The director of a medical laboratory in which serum samples are tested for human immunodeficiency virus may not disclose, directly or indirectly, the identity of any individual tested for human immunodeficiency virus in any report" HG §18-207(d).

Chapter 66, effective October 1, 1993, adds HIV infection and "CD 4+ count, if less than 200/MM3," to the list of conditions that must be reported under HG §18-205.² As explained in more detail in Part II below, Chapter 66 does not permit the report to contain the name of individuals with a low CD 4+ count or HIV infection. Rather, Chapter 66 specifies that the report is to contain a "unique patient identification number," the use of which is intended to facilitate epidemiological analysis of HIV infection and yet to preserve confidentiality.

As we understand present HIV testing practices, a person may have a test performed either confidentially or anonymously. As defined in the regulations governing HIV testing, confidential testing means that "a person uses the person's name as identification and that the person's medical records contain the person's name but are protected against disclosure as provided in the Annotated Code of Maryland." COMAR 10.52.08.02B(2). Anonymous testing, on the other hand, means "that a person does not use the person's name as identification and can only be identified through use of an assigned patient identifying number." COMAR 10.52.08.02B(1). This patient identifying number is a randomly assigned number that is different from the "unique patient identifying number" established under Chapter 66. The random number used in anonymous testing cannot be traced to the patient; the unique patient identifying number, although not itself revealing the patient's identity, will contain elements that might be traceable to the patient.

² A low CD 4+ count suggests that the individual tested is immunosuppressed, i.e., the person's immune system is compromised and not fully functional. Immunosuppression may indicate HIV infection, but it is not conclusive, because other diseases and conditions may cause immunosuppression. Centers for Disease Control, *Guidelines for the Performance of CD 4+ T-Cell Determinations in Persons with Human Immunodeficiency Virus Infection*, 41 Morbidity and Mortality Weekly Rep. No. RR-8 (May 8, 1992).

The purpose behind anonymous testing is to encourage people to be tested without fear of losing insurance or employment or experiencing repercussions from family members or others should the fact of the test or its result become publicly known despite confidentiality requirements.³ Virtually all of the test sites in Maryland perform both confidential and anonymous testing. For some test sites, the provision of anonymous testing is a condition essential to the continued funding of the site. For example, we are aware of one such clinic in Landover, which is funded by the U.S. Centers for Disease Control.

Against this background, the question has arisen whether a test site may continue to offer anonymous testing after Chapter 66 takes effect on October 1, 1993.

II

The Evolution of House Bill 460 Into Chapter 66

HG §18-205 sets forth certain requirements for the reporting of contagious diseases. It requires the director of a medical laboratory to file a report of certain contagious conditions with the local health officer. Specifically, the report must include the "name, age, sex, and residence address of the patient from whom the specimen was taken." HG §18-205(b)(ii)2. This requirement parallels those applicable to physicians and institutions. *See* HG §\$18-201(b)(3) and 18-202(c)(1).

As originally introduced, House Bill 460 added HIV infection and low CD 4+ count to the list of reportable conditions. Thus, initially, House Bill 460 recognized no distinction between the reporting of HIV infection and the reporting of other contagious diseases) all reports would identify the patient by name.

The only exception to House Bill 460's requirement of reporting by name called for the Department of Health and Mental Hygiene ("DHMH") to "designate at least 5 test sites evenly

³ Subtitle 3 of HG Title 4 contains extensive requirements governing the confidentiality of medical records. A medical laboratory director, moreover, is prohibited from compiling or distributing a list of named patients who have tested positive for HIV or who have a low CD 4+ count. HG §18-205(h)(2) (as amended by Chapter 156 (House Bill 375) of the Laws of Maryland 1993).

dispersed throughout Maryland that perform HIV tests as anonymous test sites." The bill went on to provide that "the identity of the subject of an HIV test performed at an anonymous test site ... may not be disclosed." As explained in the floor report accompanying the bill, the purpose of this provision was as follows:

In order to effectively control the spread of HIV infection, public health programs must target the populations and areas where the infection occurs with education and treatment programs. The best way to do this is to provide anonymous testing sites where high risk persons may be tested and provide demographic information without revealing their identities.

Studies have demonstrated that many high risk populations do not get tested because they are afraid their identity will become public and discrimination will result. This bill will allow these persons to be tested without revealing their names, while providing critical information concerning the spread of the disease.

The bill also repealed the confidentiality requirement of HG §18-207.⁴ Thus, as originally introduced, the only provision for anonymous HIV testing in House Bill 460 was the designation of the five anonymous test centers.

During consideration by the House and Senate, House Bill 460 underwent several significant amendments. First, and most notably, an exception to the name reporting requirement under HG §18-205 was created. Specifically, HG §18-205 was amended to provide that "reports of human immunodeficiency virus infection and CD 4+ count under 200/MM3 [shall state] the *unique patient identifying number*, age, sex, and zip code of residence of the patient" HG §18-205(b)(1)(ii)B (emphasis added). ⁵ Conforming changes were

⁴ Virtually identical legislation was introduced in the 1993 Session. *See* House Bill 416 and Senate Bill 336. Neither bill passed.

⁵ As enacted, Chapter 66 requires DHMH to develop a unique patient identifying number system to be implemented October 1, 1993. In developing the system, DHMH is to "consider the use of identifiers

made to the reporting obligations of physicians and institutions: In the case of "asymptomatic [HIV] infection," they too are to report not by name but rather by unique patient identifier. HG §§18-201(b)(3)(ii) and 18-202(c)(1)(ii). At the same time, the provision for the establishment of five anonymous test centers was deleted, and the confidentiality requirement of HG §18-207 was restored.

These amendments to House Bill 460 suggest strongly that the General Assembly sought to find a compromise that balanced the privacy interests of persons being tested against the public health policy interest in the collection of accurate demographic data concerning HIV cases.⁶ What is not at all clear from the amendments, however, is how the General Assembly intended the new reporting requirements to apply to anonymous tests sites.⁷ We turn now to an analysis of that issue.

commonly available to health care providers" and is to "consult with the Medical and Chirurgical Faculty of Maryland, the Maryland Hospital Association, the Governor's Council on HIV Prevention and Treatment, AIDS advocacy groups, and any other organizations it deems appropriate."

⁶ The collection of this information may help to control the spread of HIV infection and also may increase the amount of federal AIDS-related funding that the State receives.

⁷ This uncertainty is illustrated by the fact that legislation, House Bill 907, was introduced during the 1993 Session to make explicit that anonymous test centers were not required to use the unique patient identifying number. On the other hand, House Bill 480, also introduced in the 1993 Session, would have required anonymous test sites to use the unique patient identifying number. Neither bill passed.

Nature of Reporting Requirements

In determining whether the General Assembly intended the unique patient identifier to be used with specimens obtained at an anonymous test site, we look first to the language of the statute itself. Obviously, "what the legislature has written in an effort to achieve a goal is a natural ingredient of analysis to determine that goal." *Kaczorowski v. City of Baltimore*, 309 Md. 505, 513, 525 A.2d 628 (1987). Likewise, the General Assembly's failure to include language in a statute is at least initially suggestive of a legislative decision not to pursue an objective.

Chapter 66 simply does not address reporting by anonymous test sites. It does not say that test sites must solicit or obtain any particular information. It does not say that test sites are prohibited from submitting blood for an HIV test without the unique patient identifier. Nor does anything in the legislative record reflect these objectives in a manner suggesting an inadvertent omission from the statutory text. *Cf. Kaczorowski*, 309 Md. at 518-20 (evidence of "patent drafting error").

To be sure, it can be argued that the deletion of the requirement that DHMH designate five anonymous test sites, contained in the first reader version of House Bill 460, is evidence of the General Assembly's intent to require all test sites to use the unique patient identifier. The law as ultimately enacted, however, simply makes no reference to test sites themselves. On the basis of a bare inference alone, we are unwilling to impose a requirement on test sites that is nowhere to be found in the statutory text and nowhere discussed as an objective in the legislative history.

Chapter 66 *did* legislate requirements applicable to physicians and laboratory directors. We turn to those requirements to see whether they require a person seeking an HIV test to disclose the elements of a unique patient identifier as a prerequisite to getting the test.

The typical patient at an anonymous test site has not been referred to the site by a physician. Nevertheless, some physician necessarily has ultimate responsibility for the practices at the test site. Unless the person drawing the blood is the designee of a physician, he or she would be engaging in the unauthorized practice of medicine by drawing blood for diagnostic purposes. *See* §14-

101(j) of the Health Occupations Article. Moreover, a laboratory performs an HIV test pursuant to a proper medical order to do so. *See* HG §17-202.1(c); COMAR 10.52.08.04A.

So, as we see it, the physician who supervises the test site is the physician of the patients who seek to be tested there, at least for that limited purpose. The first issue, then, is the obligation that Chapter 66 imposes on that physician.

When a patient walks into a test site to have blood drawn, the physician in charge of the site will ordinarily have no "reason to suspect that a patient under the physician's care has an infectious or contagious disease that endangers public health" HG §18-201(a). If a patient has "asymptomatic [HIV] infection," as distinct from AIDS, the only way to know whether the patient has the disease is to test the patient's blood for the presence of antibodies. Before a positive test result is known, the physician has nothing to report, and the law imposes no obligation on the physician to obtain unique identifying information in anticipation of a possible future report. Nor does the law prohibit the physician from drawing blood (through a designee) and ordering the test without obtaining the information.

When a blood specimen from an anonymous test site arrives at a laboratory without the unique patient identifier, does Chapter 66 prohibit the laboratory from testing the specimen? The statute does not expressly impose that prohibition, and we do not believe that so significant an interference in the physician-patient relationship) preventing the physician's order for the test from being carried out) is properly inferred, at least in the absence of explicit legislative history identifying this intended result. A laboratory director, in our view, may test all specimens received in accordance with appropriate procedures. If the test is positive for HIV, the director must report whatever information itemized in HG §18-205(b)(ii) is available to the director. The director cannot report what has not been provided.

In short, Chapter 66 does not prevent the operation of sites for anonymous HIV testing.⁸

IV

⁸ We have no occasion in this opinion to consider the effect of any regulations that DHMH might adopt to implement Chapter 66.

Conclusion

In summary, it is our opinion that:

- 1. A center may take a blood specimen for purposes of HIV testing even if a patient declines to provide the information needed to create a unique patient identifying number.
- 2. A laboratory director may test a blood specimen for HIV even if the specimen is not accompanied by a unique patient identifying number.

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